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Methotrexate

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ContraindicationsPatient
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Neoplastic Diseases

Methotrexate is indicated in the treatment of gestational choriocarcinoma, chorioade mole.

Methotrexate is used alone or in combination with other anticancer agents in the tre: cancers of the head and neck, advanced mycosis fungoides, and lung cancer, partic types. Methotrexate is also used in combination with other chemotherapeutic agents non-Hodgkin's lymphomas.

Psoriasis

Methotrexate is indicated in the symptomatic control of severe, recalcitrant, disabling responsive to other forms of therapy, *but only when the diagnosis has been establis dermatologic consultation*. It is important to ensure that a psoriasis "flare" is not due disease affecting immune responses.

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Enablex
(darifenacin)
once daily 7.5mg or 15mg

Important Safety Information

Rheumatoid Arthritis including Polyarticular-Course Juvenile Rheumatoid Arti

Methotrexate is indicated in the management of selected adults with severe, active, arthritis (ARA criteria) who have had an insufficient therapeutic response to, or are in line therapy including full dose NSAIDs and usually a trial of at least one or more dis

EXHIBIT

tablets

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drugs.

Aspirin, nonsteroidal anti-inflammatory agents, and/or low dose steroids may be con increased toxicity with concomitant use of NSAIDs including salicylates has not been **PRECAUTIONS, Drug Interactions.**) Steroids may be reduced gradually in patients Combined use of methotrexate with gold, penicillamine, hydroxychloroquine, sulfase been studied and may increase the incidence of adverse effects. Rest and physiothe continued.

DOSAGE AND ADMINISTRATION

Neoplastic Diseases

Oral administration in tablet form is often preferred when low doses are being admin effective serum levels are obtained. Methotrexate sodium injection and for injection i intravenous, intra-arterial or intrathecal route. However, the preserved formulation α be used for intrathecal or high dose therapy. Parenteral drug products should be ins and discoloration prior to administration, whenever solution and container permit.

Choriocarcinoma and similar trophoblastic diseases: Methotrexate is administered o 15 to 30 mg daily for a five-day course. Such courses are usually repeated for 3 to 5 of one or more weeks interposed between courses, until any manifesting toxic symp therapy is ordinarily evaluated by 24 hour quantitative analysis of urinary chorionic g return to normal or less than 50 IU/24 hr usually after the third or fourth course and i resolution of measurable lesions in 4 to 6 weeks. One to two courses of methotrexal usually recommended. Before each course of the drug careful clinical assessment is therapy of methotrexate with other antitumor drugs has been reported as being usef

Since hydatidiform mole may precede choriocarcinoma, prophylactic chemotherapy recommended.

Chorioadenoma destruens is considered to be an invasive form of hydatidiform mole these disease states in doses similar to those recommended for choriocarcinoma.

Leukemia: Acute lymphoblastic leukemia in children and young adolescents is the n chemotherapy. In young adults and older patients, clinical remission is more difficult common.

Methotrexate alone or in combination with steroids was used initially for induction of leukemias. More recently corticosteroid therapy, in combination with other antileukei with methotrexate included, has appeared to produce rapid and effective remissions methotrexate in doses of 3.3 mg/m² in combination with 60 mg/m² of prednisone, gi 50% of patients treated, usually within a period of 4 to 6 weeks. Methotrexate in con to be the drug of choice for securing maintenance of drug-induced remissions. When supportive care has produced general clinical improvement, maintenance therapy is administered 2 times weekly either by mouth or intramuscularly in total weekly dose: given in doses of 2.5 mg/kg intravenously every 14 days. If and when relapse does i again usually be obtained by repeating the initial induction regimen.

A variety of combination chemotherapy regimens have been used for both induction lymphoblastic leukemia. The physician should be familiar with the new advances in :

Lymphomas: In Burkitt's tumor, Stages I-II, methotrexate has produced prolonged i Recommended dosage is 10 to 25 mg/day orally for 4 to 8 days. In Stage III, methot concomitantly with other antitumor agents. Treatment in all stages usually consists interposed with 7 to 10 day rest periods. Lymphosarcomas in Stage III may respond methotrexate given in doses of 0.625 to 2.5 mg/kg daily.

Mycosis fungoides (cutaneous T cell lymphoma): Therapy with methotrexate as

clinical responses in up to 50% of patients treated. Dosage in early stages is usually reduction or cessation is guided by patient response and hematologic monitoring. M administered twice weekly in doses ranging from 15 to 37.5 mg in patients who have therapy. Combination chemotherapy regimens that include intravenous methotrexate leucovorin rescue have been utilized in advanced stages of the disease.

Psoriasis, Rheumatoid Arthritis and Juvenile Rheumatoid Arthritis:

Adult Rheumatoid Arthritis: Recommended Starting Dosage Schedules

1. Single oral doses of 7.5 mg once weekly.
2. Divided oral dosages of 2.5 mg at 12 hour intervals for 3 doses given as a α weekly.

Polyarticular-Course Juvenile Rheumatoid Arthritis: The recommended starting weekly.

For either adult RA or polyarticular-course JRA dosages may be adjusted gradually achieve an optimal response. Limited experience shows a significant increase in the toxic reactions, especially bone marrow suppression, at doses greater than 20 mg/w experience with doses up to 30 mg/m²/wk (0.65 to 1.0 mg/kg/wk) may have better a side effects if methotrexate is administered either intramuscularly or subcutaneously

Therapeutic response usually begins within 3 to 6 weeks and the patient may continue or more.

The optimal duration of therapy is unknown. Limited data available from long-term initial clinical improvement is maintained for at least two years with continued therapy discontinued, the arthritis usually worsens within 3 to 6 weeks.

The patient should be fully informed of the risks involved and should be under constant supervision of the physician. (see Information for Patients under PRECAUTIONS). Assessment of hematologic, hepatic, renal, and pulmonary function should be made and laboratory tests before beginning, periodically during, and before reinstituting m PRECAUTIONS). Appropriate steps should be taken to avoid conception during m PRECAUTIONS and CONTRAINDICATIONS).

Weekly therapy may be instituted to provide doses over a range of 5 mg to 15 mg at All schedules should be continually tailored to the individual patient. An initial test dc dosing schedule to detect any extreme sensitivity to adverse effects (see ADVERSE myelosuppression usually occurs in seven to ten days.

Psoriasis: Recommended Starting Dose Schedules

1. Weekly single oral, IM or IV dose schedule: 10 to 25 mg per week until adequate
2. Divided oral dose schedule: 2.5 mg at 12-hour intervals for three doses. Dose gradually adjusted to achieve optimal clinical response; 30 mg/week should be

Once optimal clinical response has been achieved, each dosage schedule should be possible amount of drug and to the longest possible rest period. The use of t to conventional topical therapy, which should be encouraged.

HANDLING AND DISPOSAL:

Procedures for proper handling and disposal of anticancer drugs should be considered. Several guidelines on this subject have been published.¹⁻⁸ There is no general agreement recommended in the guidelines are necessary or appropriate.

HOW SUPPLIED:

Trexall™ (methotrexate tablets, USP) are available as:

5 mg: Green, oval-shaped, film-coated, scored, biconvex tablet. Debossed with 1

other side. Each 5 mg tablet contains an amount of methotrexate sodium.
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30 NDC 0555-0927-01
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7.5 mg: Blue, oval-shaped, film-coated, scored, biconvex tablet. Debossed with b on other side. Each 7.5 mg tablet contains an amount of methotrexate sodium equivalent to 7.5 mg of methotrexate.
Available in bottles of:
30 NDC 0555-0928-01
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10 mg: Pink, oval-shaped, film-coated, scored, biconvex tablet. Debossed with b on other side. Each 10 mg tablet contains an amount of methotrexate sodium methotrexate.
Available in bottles of:
30 NDC 0555-0929-01
60 NDC 0555-0929-09
100 NDC 0555-0929-02

15 mg: Purple, oval-shaped, film-coated, scored, biconvex tablet. Debossed with b on other side. Each 15 mg tablet contains an amount of methotrexate sodium methotrexate.
Available in bottles of:
30 NDC 0555-0945-01
60 NDC 0555-0945-09
100 NDC 0555-0945-02

Dispense with a child-resistant closure in a well-closed container as defined in the U.S. Pharmacopeia temperature 15°-30°C (59°-86°F) [see USP].
Protect from light.

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**Written by Pharmacists
Reviewed by Doctors**



GENERIC NAME: methotrexate

BRAND NAMES: Rheumatrex, Trexall

DRUG CLASS AND MECHANISM: Methotrexate is classified as an antimetabolite drug, which means it is capable of blocking the metabolism of ce
As a result of this effect, it has been found helpful in treating certain diseases associated with abnormally rapid cell growth, such as cancer of the breast and psoriasis. Recently, methotrexate has been shown to be effective in inducing miscarriage, for example in patients with ectopic pregnancy. This effect of methotrexate is attributed to its action of killing the rapidly growing cells of the placenta. It has also been found very helpful in treating rheumatoid arthritis, although its mechanism of action in this illness is not known. It seems to work, in part by altering aspects of immune function which may play a role in causing rheumatoid arthritis.

PRESCRIPTION: yes

GENERIC AVAILABLE: yes

PREPARATIONS: Injectable: 25mg/ml; Tablet: 2.5mg (Rheumatrex), and 5, 7.5, 10 and 15 mg (Trexall).

STORAGE: Store between 59 and 77degrees F in a sealed container, avoid lig

PRESCRIBED FOR: Methotrexate is used for cancer treatment generally in higher doses than for other uses, and is often administered intravenously or intramuscularly. Methotrexate is used to treat psoriasis, an inflammatory skin disease, as well as the arthritis that occurs in 10 percent of these patients (psoriatic arthritis). It is also used to treat active rheumatoid arthritis in adults an

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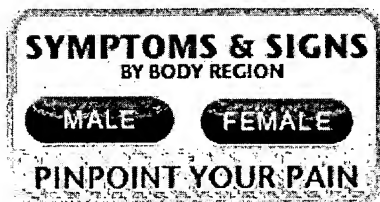
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children. It is also used to treat other rheumatic diseases, including polymyositis and systemic lupus erythematosus. Methotrexate has been used to induce miscarriage in patients with ectopic pregnancy.

DOSING: May be taken with or without food. For rheumatoid arthritis and psoriasis, the dose of methotrexate is given WEEKLY, whether by injection or orally. For psoriasis, the weekly dose is often divided into three doses given at hour intervals each week. This has been shown to be more effective, as it relate to the natural growth cycling of the skin.

DRUG INTERACTIONS: Because methotrexate can cause serious liver diseases, patients with alcoholism or liver disease should not receive it. Patients should curtail alcohol consumption while taking methotrexate. Methotrexate can suppress the body's immunity. Therefore, any symptoms of infection should be reported to the doctor. Patients with underlying immune deficiency diseases should not receive methotrexate. A dry, non-productive cough can be a result of rare lung toxicity. Methotrexate can impair fertility, decrease sperm count and cause menstrual dysfunction. Safety and effectiveness has not been established in children.

PREGNANCY: Methotrexate should not be used in pregnancy, as it can be toxic to the embryo and can cause fetal defects and spontaneous abortion (miscarriage). It should be discontinued prior to conception if used in either partner. Male patients should stop taking methotrexate at least 3 months prior to planned conception and females should discontinue use for at least one ovulatory cycle before conception.

SIDE EFFECTS: Methotrexate can be well tolerated, but also can cause severe toxicity which is usually related to the dose taken. The most frequent reactions include mouth sores, stomach upset, and low white blood counts. Methotrexate can cause severe toxicity of the liver and bone marrow, which require regular monitoring with blood testing. It can cause headache and drowsiness, which may resolve if the dose is lowered. Methotrexate can cause itching, skin rash, dizziness, and hair loss. A dry, non-productive cough can be a result of a rare lung toxicity.

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Important Safety Information

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aches, loss of appetite, and fatigue. Treatment of rheumatoid arthritis incorporates the use of first-line drugs (aspirin and corticosteroids for pain and inflammation) and second-line drugs (methotrexate and hydroxychloroquine to prevent joint destruction and promote remission). Source:MedicineNet

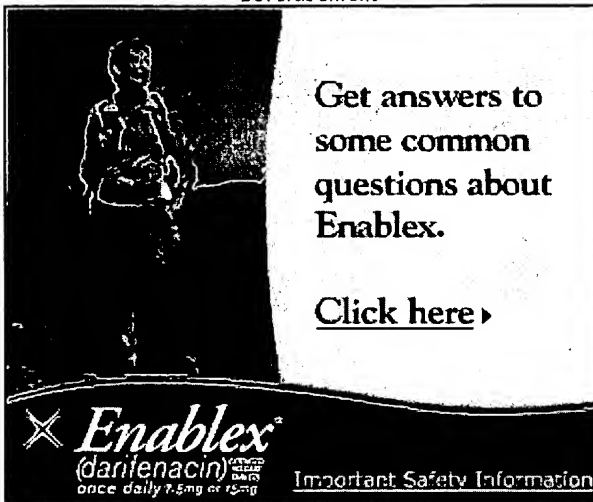
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